

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

EP. 0047735



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification <sup>3</sup>: A61B 5/14; B01L 3/14</p>	<p>A1</p>	<p>(11) International Publication Number: WO 81/01238 (43) International Publication Date: 14 May 1981 (14.05.81)</p>
<p>(21) International Application Number: PCT/GB80/00191 (22) International Filing Date: 3 November 1980 (03.11.80) (31) Priority Application Numbers: 7938039 8006866 (32) Priority Dates: 2 November 1979 (02.11.79) 29 February 1980 (29.02.80) (33) Priority Country: GB  (71) Applicant; and (72) Inventor: COOK, Ivan, John, Yason [GB/GB]; Green- lands, Teignmouth Road, Maidencombe, Torquay, Devon (GB).  (74) Agents: HODDING, H.S., et al.; Thornton &amp; Co., Nor- thumberland House, 303/306 High Holborn, London, WC1V 7LE (GB).</p>		<p>(81) Designated States: AT (European patent), AU, CH (Eu- ropean patent), DE (European patent), DK, FR (Euro- pean patent), GB, JP, LU (European patent), NL (Eu- ropean patent), NO, SE (European patent), US.  <b>Published</b> <i>With international search report</i></p>
<p>(54) Title: BLOOD SAMPLING SETS</p> <div data-bbox="422 1234 1112 1690"></div> <p style="text-align: center; font-size: 1.5em;">Best Available Copy</p> <p>(57) Abstract</p> <p>A closure for the vial (12) of a blood sampling set comprises a screw threaded cap (1) and a disc like sealing member (5, 7) which is held against the mouth of a vial (12) by the cap (1). The top end wall of the cap (1) has a central hole (4) to permit a hypo- dermic needle (11) to penetrate the sealing member (5, 7).</p>		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

<b>AT</b>	Austria	<b>KP</b>	Democratic People's Republic of Korea
<b>AU</b>	Australia	<b>LI</b>	Liechtenstein
<b>BR</b>	Brazil	<b>LU</b>	Luxembourg
<b>CF</b>	Central African Republic	<b>MC</b>	Monaco
<b>CG</b>	Congo	<b>MG</b>	Madagascar
<b>CH</b>	Switzerland	<b>MW</b>	Malawi
<b>CM</b>	Cameroon	<b>NL</b>	Netherlands
<b>DE</b>	Germany, Federal Republic of	<b>NO</b>	Norway
<b>DK</b>	Denmark	<b>RO</b>	Romania
<b>FI</b>	Finland	<b>SE</b>	Sweden
<b>FR</b>	France	<b>SN</b>	Senegal
<b>GA</b>	Gabon	<b>SU</b>	Soviet Union
<b>GB</b>	United Kingdom	<b>TD</b>	Chad
<b>HU</b>	Hungary	<b>TG</b>	Togo
<b>JP</b>	Japan	<b>US</b>	United States of America

Best Available Copy

- 1 -

Blood Sampling Sets

This invention relates to blood sampling sets of the type comprising a sealed vial, usually of transparent or translucent glass or plastics, whose interior is partially evacuated, a double ended hypodermic

5 needle and a holder comprising a barrel which accommodates one end portion of the vial and which also holds the needle, with one end thereof extending into the barrel.

10 In use of such sets, one end of the needle, mounted on the barrel, is inserted into the patient, and the other end is caused to pierce a seal on the vial, which is guided and supported by the barrel, so that blood is drawn into the vial to satisfy the partial vacuum.

15 In known sets of this type, the vial is usually sealed by an internal plug of elastomeric material and such sets are satisfactory during blood sampling and in storage and transit of the sealed vial with its blood sample.

20 However, problems can and do arise at the blood testing stage when the vial is opened for access to the blood sample. Due to changes in internal volume which are unavoidable when removing an internal plug, small droplets of blood are inevitably ejected from the  
25 vial and fall to the work surface. Additionally, blood

Best Available Copy



- 2 -

adhering to the plug often drops to the work surface causing risk of contamination by pathogens. An "aerosol effect" is also said to occur when the internal plug is removed in which finely dispersed droplets of blood ejected into the atmosphere may be inhaled causing risk of transmission of disease. It is also difficult to remove the internal plug by hand without contaminating the fingers and the surface onto which the plug is placed.

10           The present invention aims at the provision of closure means for a vial for use in a blood sampling set of the general type first described which closure means obviates or reduces the above mentioned risk of contamination.

15           In accordance with a feature of the invention there is provided a closure member for a vial of a blood sampling set, the closure member carrying a liner of elastomeric material which, when the closure member is in position on the vial neck is held in sealing engagement against the mouth of the vial, and the closure member having a hole through its top to permit the passage of a hypodermic needle through the top and liner.

20           The closure member may for example be a screw cap for use with a vial having a screw neck or a suitable snap closure.

          A vial fitted with the closure member is used in the same manner as the known vial described above to effect sampling, but in the laboratory the action employed to open the vial virtually eliminates droplet and "aerosol effect" which is associated with the removal of an internal plug; furthermore any blood adhering to the liner is shielded from contact by the side wall of the closure member.

30           A form of closure member is described below, by way of example, with reference to the accompanying

Best Available Copy



- 3 -

part sectional elevation drawing.

The illustrated closure member comprises a cap 1 which is preferably moulded of a rigid plastics material, and has a simple inverted cup shape with an internally screw-threaded side wall 2 and a top wall 3 having a central hole 4. The cap 1 carries a liner 5 formed as a simple disc of rubber or other elastomeric material which is fitted in the upper region of the cap against the underside of the top wall.

10 The cap 1 is applied to a vial having a screw-threaded neck or lug (annular ring) and the cap holds the liner in sealing engagement with the mouth of the vial.

Partial evacuation of the vial is effected by inserting a hollow needle through the hole 4 and the liner 5 and withdrawing air through the needle. When the needle is withdrawn, the hole made in the liner by the needle is self-sealing by virtue of the resilience of the liner material, and the vial is thus able to sustain its internal partial vacuum until required for use in blood sampling.

The vial is then used in conventional manner to take a blood sample and transferred to the laboratory where the cap is removed to permit access to the sample. 25 The droplet and "aerosol effect" is obviated since the face-to-face seal between the liner and the vial is gently and easily broken by unscrewing the cap. This is in contrast to the removal of a conventional internal plug which involves alteration in the internal volume of the space above the surface of the blood and a sudden 30 inrush of air when the seal is finally and abruptly broken.

Furthermore, the drop of blood which will usually adhere to the interior of the liner is shielded 35 from contact by the side wall 2 of the cap.

Best Available Copy



- 4 -

The remaining components of a blood sampling set including the above described vial may be conventional in themselves and are indeed preferably standard components. The double ended needle may be  
5 valved or unvalved in known manner.

In the alternative embodiment shown in Figure 2, the liner is modified in two main respects. First, the liner has a downwardly projecting plug section 7 having a chamfered side wall 8 to assist in pre-location  
10 of the liner, and the periphery 9 of the liner is chamfered upwardly and inwardly to assist its location and retention in the cap 1.

With this construction, the liner may first be loosely located over the mouth of the vial, the plug  
15 section assisting in centering the liner, and a batch of vials with loose liners is placed in a vacuum chamber. On evacuation of the chamber, air is extracted from the interior of each vial, the liner lifting slightly to permit the escape of air. When the chamber  
20 is re-pressurised, the pressure difference causes the liner to seal against the mouth of the vial and thereby retain the partial vacuum.

The evacuated vials are then removed from the pressure chamber and the screw caps are applied with  
25 slight interference between the screw threads of the cap and the chamfered edge of the liner, which is slightly compressed in the process. When the cap is screwed fully home, the liner is firmly engaged in the cap and after taking a blood sample, in the manner  
30 described above, the cap is subsequently unscrewed as before retaining the liner in position where it is shielded from accidental contact by the side wall of the cap.

The vial and closure can, however, alternatively  
35 be evacuated after screwing on the cap by use of a

Best Available Copy



- 5 -

hollow evacuating needle as described in relation to the embodiment of Figure 1.

The chamfered design shown in Figure 2 has been found extremely effective in ensuring that the  
5 liner is retained to the cap on opening the vial, the slight compression and consequent frictional grip is adequate for this purpose since at the time of opening the vial, following blood sampling, the interior of the vial is at atmospheric pressure. However, if a more  
10 positive retention were required, the cap may have an undercut groove on the base of the screw thread or a narrow annular rib may be provided to trap the periphery of the liner.

The closure member, instead of taking the form  
15 of a screw cap, may for example take the form of a snap-on or crimped lid retained by an annular ring of suitable section on the outside of the vial neck. If the cap is screw threaded or snap-fitting, a tamper-proof capsule may be applied to provide a visual  
20 indication of possible loss of vacuum or sterility of the vial.

For the sake of completeness, a blood sampling set is illustrated in Figure 3. It comprises a holder in the form of a standard barrel 10 open at one end and  
25 fitted at the opposite end with a double-ended needle 11, and a vial 12 fitting easily in the bore of the barrel 10 and having its inner end closed by a cap 1 and liner of any of the forms described and/or illustrated herein.

Best Available Copy



- 6 -

## CLAIMS:

1. A blood sampling set including a holder carrying a double ended needle and a partially evacuated vial having a removable cap of inverted cup shape adapted for secure but releasable engagement over the neck of the vial, and a liner of elastomeric material located within the cap against its transverse end wall so as to seal against the mouth of the vial when the cap is in position on the neck of the vial, the cap having a hole through its end wall to permit the passage of one end of the said needle through the top and liner.
2. A blood sampling set according to claim 1 in which the liner takes the form of a relatively thin disc fitting closely within the interior of the cap.
3. A blood sampling set according to claim 1 or 2, wherein the side wall of the cap is internally screw threaded for cooperation with a vial having an externally screw threaded neck.
4. A blood sampling set according to claim 1 or 2, wherein the side wall of the cap is adapted for snap fitting engagement over the neck of a cooperating vial.
5. A blood sampling set according to any preceding claim, wherein the liner has a circular plug section formed on its inner surface for centralising the liner relative to the vial.

Best Available Copy





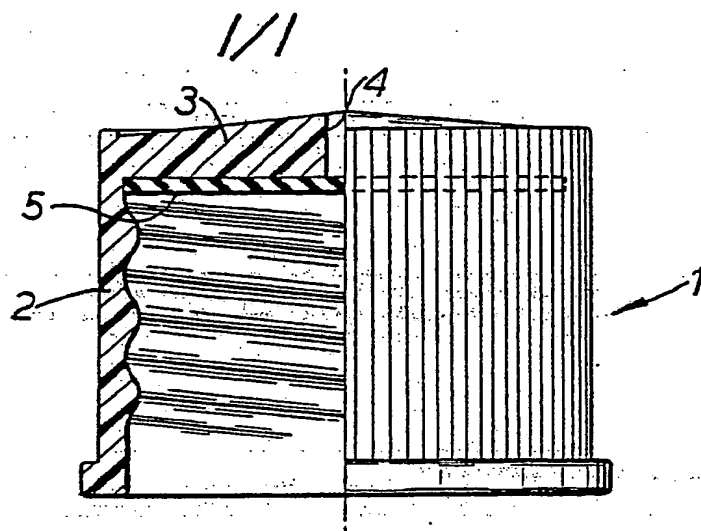


FIG. 1.

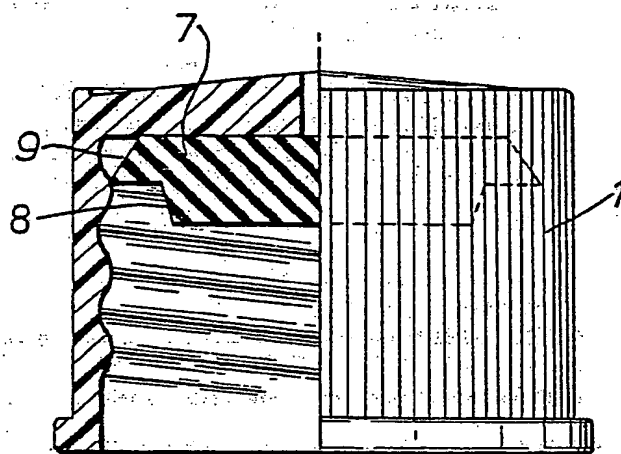
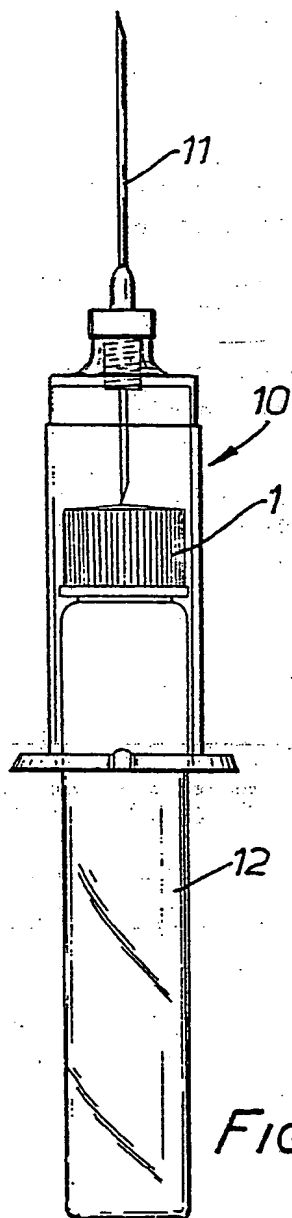


FIG. 2.

Best Available Copy  
FIG. 3.

International Application No PCT/GB 80/00191

Form PCT/ISA/210 (second sheet) (October 1977)

# Best Available Copy